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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/518,859
Filing Date: December 17, 2004
Appellant(s): INOUE ET AL.

Paul J. Esatto, Jr
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/12/2010 appealing from the Office action mailed 8/18/2009

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

Claims 43, 44, 51-54, 131 and 133 are under Appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6018033	Chen et al	1-2000
6146655	Ruben	11-2000
2004/0093080	Helmus et al	5-2004
2004/0059101	Weissler et al	3-2004
WO 02/16378	Weissler et al	2-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Issue I

Claims 43-44, 49, 51-54 and 63-65 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US patent 6018033) in view of Ruben (US 6146655) and further view of Helmus et al (US publication 2004/0093080 and WO 0154745) (all cited in the previous Office Action) (necessitated by Amendment)

Regarding Claims 43-44, 53-54 and 65 Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12,Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples II1-1 and 111-2 and Column 7, line 35).

Chen explicitly teaches classical Diels-Alder reaction between olefin and diene, which is thermoreversable (see Column 6, line 35, meeting the limitations of claims 44, 47 and corresponding limitations of claims 48-50). The same Diels-Alder reagents (diene and dienophile, i.e vinyl) disclose in the Specification of the Application examined (see line 0056). Since thermo-reversability depends on the particular structure of Diels Alder reagents (not the nature of the base polymer) the same temperature range of cleavage of the covalent bond is expected.

In other words, the cleavage/restoration cycle occurs between Diels Alder reagents, attached to the polymer chain. The nature of the polymer does not influence the reaction above.

Regarding Claims 51 and 63, Chen discloses cross-linked density in terms of Swelling Ratio. This ratio changes within a broad range of 5-90%. According to Flory, cross-link frequency can be calculated from the above parameter (more crosslink frequency corresponds with less swelling ratio). In examiner's opinion, Chen's composition internally possesses cross-linked density to meet the limitations of the above Claims.

Regarding Claims 52 and 64, Chen teaches a biodegradable resin can contain linear and branched structure (column 5, line 25).

Chen does not teach that his composition is moldable.

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

The advantage of Ruben is that the above gel can be molded in the shape of water –permeable porous envelope (see Abstract), which can be used in oral

applications not only as drug delivery carrier, but also as reverse-osmotic membrane, effective for saliva removal (see column 9, line 60).

Therefore, it would have been obvious to a person of ordinary skills to use Chen's polysaccharides in moldable drug delivery compositions, since it allows increasing applicability of the material.

Regarding limitation of claim 43, Chen or Ruben does not disclose a biodegradable resin based on polylactic acid.

Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068). Helmus teaches that the above copolymer can be used as a carrier for bioactive material (see line 0122). Note that Helmus's composition has the same primary application as Chen's one. Helmut teaches that encapsulation of biologically active material can be performed in hot melt (see line 0130).

Helmus teaches that polysaccharides and polylactic acid can be equally used in thermoreversible gel compositions (see lines 0114 and 0116).

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also also

In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

It would have been obvious to a person of ordinary skills in the art to use a modified polylactic acid derivative in Chen's composition, since the esters, based on the above material are known material based on its suitability for its intended use.

Issue II

Claims 131 and 133 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Ruben and Helmus as applied to claims 43-44, 47-49, 51-57, 59-61 and 63-65 above and further view of Weissler et al (WO 2002/016378, cited with equivalent US 2004/0059101)

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12,Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples II1-1 and 111-2 and Column 7, line 35).

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068). Helmus teaches that the above copolymer can be used as a carrier for bioactive material (see line 0122). Note that Helmus's composition has the same primary application as Chen's one. Helmut teaches that encapsulation of biologically active material can be performed in hot melt (see line 0130).

Helmus teaches that polysaccharides and polylactic acid can be equally used in thermoreversible gel compositions (see lines 0114 and 0116).

Chen or Ruben or Helmus does not teach cyclic dienes as Diels-Alder reagents.

Weissler teaches biodegradable reversible system (see line 0008), based on polysaccaride (see line 0011) and cyclic or acyclic diene (see line 0006). Weissler teaches that the above reagents produce a compound with well controlled structure and quantitative yield (see line 0008). Also, Weissler discloses that the reaction can be performed at mild conditions (see line 0008).

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

Therefore, it would have been obvious to a person of ordinary skills in the art to interchangeably use cyclic and alycyclic dienes in Chen's composition, modified with Ruben, since these compounds are known material based on its suitability for its intended use.

Note that both Weissler and Chen apply their compound for drug delivery system and other medical purposes (see Weissler, line 0002 and Chen, Col27, line 30).

(10) Response to Argument

Issue I

Appellants submits "that the biodegradable moldable resin of the present invention as recited in independent claim 43, is prepared from polylactic acid or polybutylene succinate, whereas Chen's foams and gels are prepared from saccharide. When the backbone polymers are different, so are the chemistries. The Diels-Alder type functional groups of the present invention covalently bond at temperatures lower than 100°C and split at over 120°C, whereas Chen's foams and gels expand their polymer chains and cells when absorbing water. There is no chemical cleavage in this expansion".

Examiner disagrees. Chen explicitly discloses a thermo-reversible biodegradable polymer (see Abstract). Figures 12(A-C) demonstrate that the cleavage takes place at the temperatures of above 120C.

Regarding Figures 12(A-C), Appellant argues that the term "thermoreversible" means, in this context, relaxation and restriction of the polymer chain and cells, but not chemical bond and cleavage of the functional groups.

Examiner disagrees. Chen explicitly teaches classical Diels-Alder reaction between olefin and diene, which is thermoreversable (see Column 6, line 35). The same Diels-Alder reagents (diene and dienophile, i.e vinyl) disclose in the Specification of the Application examined (see line 0056). Since thermo-reversibility depends on the particular structure of Diels Alder reagents (not the nature of the base polymer) the same temperature range of cleavage of the covalent bond is expected.

In other words, the cleavage/restoration cycle occurs between Diels-Alder reagents, attached to the polymer chain. The nature of the polymer does not influence the reaction above.

Appellant argues that Examples III-1 and III-2 do not disclose polylactic acid, polybutylene succinate and the Diels-Alder type functional groups.

Examiner disagrees. Chen explicitly teaches classical Diels-Alder reaction between olefin and diene, which is thermo-reversable (see Column 6, line 35).

Secondary reference (Helmus) discloses polylactic acid.

Appellant submits that Chen and Helmus belong to different fields of endeavor.

This is incorrect. Helmus teaches that the above copolymer can be used as a carrier for bioactive material (see line 0122). Note that Helmus's composition has the

same primary application as Chen's one. Helmut teaches that encapsulation of biologically active material can be performed in hot melt (see line 0130).

Appellant admits that Helmus clearly teaches reversible composition and polylactic acid (see Appeal Brief, page 15). However, Appellant argues that the Reference does not disclose the above features in its preferred embodiments.

According to MPEP 2123, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments (see also *In re Susi,* 440 F.2d 442, 169 USPQ 423 (CCPA 1971), *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) , *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

To summarize the above arguments, Chen teaches biodegradable resin with Diels-Alder agent, equal to one of the Appellant (i.e. diene and olefin), which provides the same thermo-reversible properties in both cases. Secondary reference (Helmus) discloses reversible system based on polysaccharide (the same polymer as one of Chen) and claimed polylactic acid as a biodegradable polymer.

Issue II

Appellant submits that Wiessler discloses polysaccarides, but not claimed polylactic acid or polybutylene succinate. Appellant further states that " When the primary polymers are different, so are the chemistries; the present invention experimentally manifests the data on cleaving temperature, heat resistance,

biodegradability, recycling property, molding property and wet resistance (see table 2 in the present application)".

However, Wiessler applied in the rejection solely for the purposes to demonstrate that cyclic dienes can be used as a part of Diels-Alder system. Linear, cyclic and alicyclic dienes are classical Diels Alder reagents. The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

GL

/GREGORY LISTVOYB/

Examiner, Art Unit 1796

Conferees:

/James J. Seidleck/

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